UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BOSTON SCIENTIFIC CORPORATION SECURITIES LITIGATION	Master Case No. 05-11934-JLT

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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PRELIMINARY STATEMENT

Boston Scientific Corporation ("Boston Scientific" or the "Company") is a worldwide developer, manufacturer, and distributor of medical devices used in a broad range of interventional medical specialties. This securities fraud action was commenced in a "rush to the courthouse": five complaints were filed just after Boston Scientific received FDA "warning letters" (which the FDA itself describes as merely "informal and advisory" communications) concerning technical monitoring and reporting issues at three of the Company's 26 worldwide facilities. In those complaints, the theory of securities fraud was that the Company's disclosures had focused too much on the risks presented by the Company's various litigation matters, in an attempt to distract investors from the regulatory compliance risks faced by the Company. In fact, the Company's public filings expressly cautioned of regulatory compliance risks, and the complaints did not (and could not) allege that the warning letters in any way interfered with the ongoing manufacture and distribution of any of the Company's medical devices. Faced with this reality, in the Consolidated Amended Complaint (the "Complaint" or "CAC") plaintiff has completely changed the theory and allegations of the original complaints. But it improves upon them not at all.

Plaintiff in the new Complaint treats the FDA warning letters as barely an afterthought, and focuses instead on three matters well known to the investing public at the time the original complaints were filed, but which were nowhere mentioned in any of them. Plaintiff's initial silence respecting those matters is an eloquent testament to their unsuitability as the foundation for a securities fraud claim.

First, 180 degrees contrary to its original theory, plaintiff now asserts that the Company "downplayed" its litigation-related risk disclosures regarding two matters: a civil lawsuit, and an investigation by the United States Attorney. Both matters were repeatedly disclosed in the Company's public filings, and were the frequent subject of cautionary statements. For example, the Company stressed that "There can be no assurance that" the litigation or investigation "will result in an outcome favorable to the Company," and the

Company made clear that a negative outcome could adversely affect it. Ultimately, the matters were settled. Plaintiff's theory is not (and could not be) that these matters presented undisclosed risks. Instead, it seems to assert that defendants "knew" the matters had "merit" and therefore should have disclosed the "certainty" that the Company "would" have to pay to resolve them. Under this rationale, a public company that is defending litigation or involved in a government investigation would have to publicly confess in order to avoid later liability in the event of an adverse ruling or a settlement. There is no such rule. Nor is there any factual basis in the Complaint to support an inference that anyone at Boston Scientific had more certainty than market participants about the potential dollar exposure from those legal matters. Indeed, it was widely reported in the press that the litigation settlement was on better terms than expected by the securities markets.

Next, plaintiff alleges that Boston Scientific failed to adequately disclose problems it was experiencing with one of its medical devices in the spring and summer of 2004. The facts as pleaded, however, establish that the problems initially reported were limited in number and fully disclosed. Later in 2004, some of the devices were recalled. Plaintiff uses the subsequent recall as an illogical basis to infer that Boston Scientific must have known about more substantial problems earlier. This kind of hindsight has been rejected as a basis to plead fraud for decades. Gross v. Summa Four, Inc., 93 F.3d 987, 991 (1st Cir. 1996); Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978).

Finally, plaintiff alleges implausibly that references to the Company's "commitment to quality" were false. It is remarkable that plaintiff would even attempt to predicate a securities fraud claim on such "corporate puffery," which is inherently immaterial and cannot be actionable in any context. This is particularly true here, where plaintiff supposes that such puffery could be rendered false by the existence of FDA letters that were published by the FDA and available to the securities markets at the same time that they were available to the Company. Plaintiff can hardly make out a fraud claim on the theory that the securities markets were misled by the omission of facts contemporaneously known to them.

ALLEGATIONS OF THE COMPLAINT[1]

The Complaint alleges that from March 31, 2003, through August 23, 2005, the putative class period, Boston Scientific and the Individual Defendants[2] made a series of misstatements and omissions respecting four different subjects: (1) the Company's civil lawsuit with Medinol Ltd. ("Medinol"); (2) a Department of Justice ("DOJ") investigation arising out the Company's voluntary recall in 1998 of certain of its "NORS" coronary stents (coronary stents are tiny, mesh tubes implanted in patients to prop open arteries to facilitate blood flow from the heart); (3) the Company's 2003-04 introduction and later recall of some of its Taxus coronary stents; and (4) the Company's quality systems and the FDA warning letters.

1. The Medinol Litigation

In 2001, two years before the class period, Medinol sued Boston Scientific in the United States District Court for the Southern District of New York. (CAC ¶ 57.) Boston Scientific counterclaimed. The dispute arose out of the parties' 10-year supply agreement, pursuant to which Boston Scientific was granted the exclusive right to market coronary stents designed and manufactured by Medinol. Boston Scientific claimed that Medinol had failed to meet Boston Scientific's demand requirements, and Medinol claimed that Boston Scientific improperly tried to copy Medinol's stent designs. As explained by the Hon. Alvin Hellerstein, who presided over the case, the parties' competing claims presented "complex issues of breach of contract, misappropriation of trade secrets, and many other statutory and common law wrongs." Medinol Ltd. v. Boston Scientific Corp., 346 F. Supp. 2d 575, 581 (S.D.N.Y. 2004). The case was litigated for nearly five years, and eventually settled in 2005. (App. Ex. L.)

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[1] The Complaint's well-pleaded factual allegations and reasonable inferences therefrom are accepted as true for purposes of a motion to dismiss, but the Court "is free, however, to disregard bald assertions, unsupportable conclusions, and opprobrious epithets." In re Credit Suisse First Boston Corp., 431 F.3d 36, 45 (1st Cir. 2005). In addition, documents that are central to plaintiff's claims appropriately may be considered on a motion to dismiss. See 15 USC § 78u-5(e) (2006); see also Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co., 267 F.3d 30, 33 (1st Cir. 2001); Beddall v. State St. Bank & Trust Co., 137 F.3d 12, 16-17 (1st Cir. 1998). Copies of such documents are included in the accompanying Appendix of Public Records (cited herein as "App. Ex. __").

[2] According to the Complaint, an Executive Committee comprised of the Individual Defendants is responsible for the day-to-day management of the Company. (CAC ¶ 14.) The Individual Defendants are Peter M. Nicholas, James R. Tobin, Lawrence C. Best, Paul A. LaViolette, Fredericus A. Colen, Stephen F. Moreci, Paul W. Sandman, James H. Taylor, Jr., and Robert G. MacLean.

Throughout the class period, the Medinol litigation was disclosed year after year in Boston Scientific's 10-K:

> On April 5, 2001, Medinol Ltd. (Medinol) filed a complaint against the Company and certain of its current and former employees alleging breaches of contract, fraud and other claims. The suit was filed in the U.S. District Court for the Southern District of New York seeking monetary and injunctive relief. On April 26, 2001, Medinol amended its complaint to add claims alleging misappropriation of trade secrets in relation to the Company's Express(TM) stent development program. Medinol seeks monetary and injunctive relief, as well as an end to the Company's right to distribute Medinol stents and to gain access to certain Company intellectual property. On April 30, 2001, the Company answered and countersued Medinol and its principals, seeking monetary and injunctive relief.

(App. Ex. A at Exhibit 13.1, p. 41; Ex. B at Exhibit 13.1, p. 67; Ex. C at p. 65.) The Company cautioned that a favorable outcome was not assured, and that a negative outcome could adversely affect it. (App. Ex. A at Exhibit 13.1, p. 36; Ex. B at Exhibit 13.1, p. 60; Ex. C at p. 62.) Further, its disclosures included procedural status updates to the litigation. (See, e.g., App. Ex. C at p. 65 ("On December 2, 2004, the Court granted summary judgment in part and denied summary judgment in part, dismissing the remaining individuals and dismissing all of the jury claims.").)

Market commentators had analyzed the litigation and viewed the potential exposure to Boston Scientific at over $1.5 billion. (App. Ex. M.) Accordingly, when the case was settled for $750 million (CAC ¶ 71), the market viewed the settlement as consistent with predictions and generally a positive development for the Company. (See App. Exs. N-P.)

2. The Department of Justice Investigation

In August 1998, more than four years before the class period, Boston Scientific introduced its "NORS" coronary stents. In October of that year, the Company voluntarily recalled certain of those stents. (App. Ex. W at p. 3.) The Company no longer manufactures the NORS stent. (CAC ¶ 81.)

In November 1998, the United States Department of Justice began an investigation of the NORS recall. (CAC ¶ 75.) As plaintiff describes it, the investigation

concerned whether the Company "took an improper risk" in marketing its NORS stents. (Id. ¶ 79.) The investigation continued for many years, and both the Company and two of its senior officers were named as targets of the investigation. (Id. ¶ 75.)

Like the Medinol litigation, the DOJ investigation and the risk of an adverse outcome were disclosed in all of Boston Scientific's 10-K filings throughout the class period:

> In October 1998, the Company recalled its NIR ON(R) Ranger(TM) with Sox(TM) coronary stent delivery system following reports of balloon leaks. Since November 1998, the U.S. Department of Justice has been conducting an investigation primarily regarding: the shipment, sale and subsequent recall of the NIR ON(R) Ranger(TM) with Sox(TM) stent delivery system; aspects of the Company's relationship with Medinol, the vendor of the stent; and related events. The Company and two senior officials have been advised that they are targets of the federal grand jury investigation, but that no final decision has been made as to whether any potential charges would be brought. Although the Company has contested certain procedural matters related to the conduct of the investigation, the Company and the two senior officials have agreed to extend the applicable statute of limitations, which may result in the investigation continuing into mid 2004 or beyond. There can be no assurance that the investigation will result in an outcome favorable to the Company, that charges would not be brought, or that the Company would not agree to a further extension of the statute.

(App. Ex. B at Exhibit 13.1, pp. 68-69; see also App. Ex. A at Exhibit 13.1, p. 42; Ex. C at p. 67.) An expected settlement of the matter was announced in February 2005. (App. Ex. Q.) In June 2005, a civil settlement was concluded, in which Boston Scientific agreed to pay $74 million. (CAC ¶ 83.) The settlement did not involve any admission of liability or wrongdoing by the Company, and the DOJ did not bring any criminal charges against the Company or any of its officers. (See id.) As the DOJ explained in announcing the settlement: "This case does not involve any risk to those patients who had one of these stents implanted in their bodies. The issue is not, and was never, whether the stent performed properly." (App. Ex. W at p. 2.)

3. The Taxus Stent Recall

Well before the beginning of the class period, Boston Scientific began development of a drug eluting stent called the TAXUS® Express Paclitaxel-Eluting Monorail® Coronary Stent System ("Taxus"). (CAC ¶ 86.) It was introduced in Europe in the first quarter

of 2003. (Id. ¶ 87.) The FDA approved Taxus for marketing and distribution in the United States in March 2004. (Id. ¶ 92.)

On April 20, 2004, the Company reported that "there have been worldwide 40 complaints in the aggregate" concerning the Taxus stents. (CAC ¶ 93.) On May 7, 2004, Boston Scientific cautioned in its 10-Q that its success with drug eluting stents could be adversely impacted by "unexpected variations in clinical results or product performance," and disclosed that "[t]he Company is currently reviewing a limited number of reports related to balloon withdrawal difficulty during TAXUS angioplasty procedures." (App. Ex. D at p. 22.)

On July 2, 2004, Boston Scientific announced a recall of 200 Taxus stents. (CAC ¶ 97.) Additional recalls occurred later in 2004, and Boston Scientific eventually recalled a total of 99,000 Taxus stents. (Id. ¶¶ 100, 102, 103.) Boston Scientific continues to manufacture and sell Taxus stents. (App. Ex. E at pp. 23-24.)

4. The FDA Warning Letters

The medical devices manufactured by Boston Scientific are subject to regulation by the FDA, and the FDA routinely conducts field inspections. (App. Ex. A at p. 22; Ex. B at p. 17; Ex. C at pp. 11-12.) It is common practice after these inspections for the FDA to send a "warning letter" detailing its findings. (See App. Ex. R at 4-2.)[3] FDA regulations state that these letters are "informal and advisory" and are not "final agency action." (Id. at 4-1-1.) Under FDA practice, the letters are posted immediately on the FDA's website. (Id. at 4-1-13.)

On May 18, 2005, the FDA wrote to Boston Scientific concerning an inspection at its Watertown, Massachusetts facility and noting regulatory deficiencies. (CAC ¶ 110.) This letter was immediately published on the FDA website, in accordance with FDA procedures. On August 1, 2005, Boston Scientific received a letter from the FDA concerning certain deficiencies at its Glens Falls, New York facility. (Id. ¶ 118.) This letter also was immediately posted on the FDA's website. On August 16, 2005, a Reuters article discussed the letter, noting that "[t]he

[3] The Court may take judicial notice of agency rules, regulations, and manuals on this motion to dismiss. See, e.g., U.S. v. Huguenin, No. 94-1119, 1994 U.S. App. LEXIS 18692, at *7 (1st Cir. July 22, 1994); Northern Heel Corp. v. Compo Indus., 851 F.2d 456, 468 (1st Cir. 1988); Sears v. U.S., 264 F. 257, 261 (1st Cir. 1920).

FDA sends dozens of warning letters each year." (Id. ¶ 122.) On August 10, 2005, Boston Scientific received a letter related to a third facility, in Quincy, Massachusetts. (Id. ¶ 121.) Consistent with FDA regulations, this letter, like the previous two, was immediately published on the FDA's website. On August 23, 2005, thestreet.com published an article discussing this third letter. (Id. ¶ 124.)

The Complaint does not (and cannot) allege that the FDA took any type of enforcement action against the Company (e.g., product seizures, injunctions, or fines) as a result of these letters, or that the letters impacted or interfered with the Company's ability to manufacture, distribute, or market any of its products.

ARGUMENT

I. Summary Of Argument

To state a claim under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), a plaintiff must identify (1) a material misrepresentation or omission, (2) made with scienter, (3) in connection with the purchase or sale of a security, (4) on which the plaintiff relied, (5) to his detriment. Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341 (2005). Under the Private Securities Litigation Reform Act of 1995 (the "Reform Act"), the complaint must "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1) (2006). In addition, Rule 9(b) requires that "all averments of fraud or mistake … shall be stated with particularity." Fed. R. Civ. P. 9(b).

As detailed below, the Complaint fails to plead the threshold prerequisite for a securities fraud claim – an actionable misstatement or omission. Plaintiff purports to identify several supposed misstatements, but does not explain why each is actionable. Of course, individual statements that are not otherwise actionable do not become so merely through accumulation. See In re Boston Tech., Inc. Sec. Litig., 8 F. Supp. 2d 43, 55 (D. Mass. 1998) ("It is not the law that a 10b-5 complaint is to be judged on the basis of the general flavor derived from an issuer's collective statements over a long period of time."). All of the claimed misstatements – including those related to the Medinol litigation and the DOJ investigation,

those related to the Taxus recall, and those related to the FDA warning letters – suffer from common flaws. Many of the claimed misstatements, for example, are "puffing" expressions that are immaterial as a matter of law. Others are presented without specific facts indicating how the statements were supposedly false when made, as required by the Reform Act and Rule 9(b). When plaintiff attempts to provide an explanation, it impermissibly pleads "fraud by hindsight" – contending that defendants "must have known" earlier about that which occurred later. Most of the claimed misstatements were "forward-looking" statements under the Reform Act, and thus statutorily immune from attack. Finally, plaintiff implausibly (and impermissibly) asserts that a number of the challenged statements were false because they omitted information demonstrably known to the market.

In addition to failing to plead any actionable misstatement or omission, the Complaint fails to plead scienter – i.e., knowing falsity – with the requisite particularity. The Reform Act requires that a securities fraud complaint identify specific facts giving rise to a strong inference of scienter as to each defendant. 15 U.S.C. § 78u-4(b)(2). It is not enough merely to allege that by virtue of their positions in the Company the Individual Defendants "must have known" the allegedly misleading statements were false. Nor is it enough to catalogue their stock sales.

Finally, the Complaint is deficient because it fails to plead loss causation, in other words, "a causal connection between the material misrepresentation and the loss." Dura, 544 U.S. at 342. Where, as here, the claimed loss was the result of materialization of a disclosed risk, no claim for securities fraud will lie. See Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 173 (2d Cir. 2005), cert. denied, 126 S. Ct. 421 (2005).

II. The Complaint Fails To Allege With Particularity Any Actionable Misstatement Or Omission Respecting The Medinol Litigation Or The DOJ Investigation

Plaintiff challenges the following statements respecting the Medinol litigation, made before the District Court's summary judgment ruling in that case:

- Warnings in the Company's SEC filings that the Company's performance could be adversely affected by a negative outcome. (CAC ¶¶ 60-61.)

- A statement by Mr. Sandman that "I don't frankly think that [Medinol's theft of trade secrets] theory is going to hold up." (Id. ¶ 63.)

Plaintiff also claims the following statements, made after the District Court's summary judgment ruling, are actionable:

- A statement by Mr. Tobin that the case "has been brought down to this thing which is a contract dispute. So sooner or later that will get solved." (CAC ¶ 64.)
- A statement by Mr. Best that "it's not a patent issue, it's not [an] intellectual property issue, it's primarily a straight out contract, breach of contract issue." (Id. ¶ 65.)
- A statement by Mr. Donovan that "As the ruling states, this is essentially a breach of contract case, which alleges 'grandiose estimates of damage' that are unlikely to succeed." (Id. ¶ 68.)

Regarding the DOJ investigation, plaintiff challenges the following statements:

- Statements in the Company's SEC filings that it believed it had "acted responsibly and appropriately" with respect to the matter under investigation. (CAC ¶¶ 75, 83.)
- Statements in the Company's public filings that the outcome of the DOJ investigation "may" adversely affect the Company. (Id. ¶ 82.)
- Statements during an analyst call that "I don't see any evidence of a connection [between the DOJ investigation and Taxus] ... I just haven't seen any nexus that relates to Taxus." (Id. ¶ 81.)
- Similar statements during the same analyst call: "it [the DOJ investigation] doesn't focus on any product we are selling today. We don't believe it implicates our business, as you know it today." (Id.)

Plaintiff's challenges to these statements do not state a claim because with respect to each plaintiff fails to comply with at least one of three critical pleading requirements. First, the Reform Act "requires plaintiffs to specify the reason or reasons why a *particular* statement is false or misleading." In re Credit Suisse First Boston Corp., 431 F.3d 36, 50 (1st Cir. 2005) (emphasis in original). This requires identification of facts showing just why a statement was materially misleading. Greebel v. FTP Software, Inc., 194 F.3d 185, 193-94 (1st Cir. 1999). This cannot be accomplished by hindsight – pointing to subsequent events (i.e., the settlements in the Medinol litigation and respecting the DOJ investigation) as "proof" that earlier statements were false when made. Gross, 93 F.3d at 991. Second, a plaintiff cannot plead securities fraud

by challenging subjective characterizations or "standard" hyperbole. In re No. Nine Visual Tech. Corp. Sec. Litig., 51 F. Supp. 2d 1, 20 (D. Mass. 1999). The First Circuit has repeatedly rejected as "clearly inactionable puffing" challenges to statements "that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available." Shaw v. Digital Equip. Corp., 82 F. 3d 1194, 1217 (1st Cir. 1996); see Serabian v. Amoskeag Bank Shares, 24 F.3d 357, 361 (1st Cir. 1994).[4] Third, a plaintiff that claims expressions of opinion were false "must, for each allegedly false opinion, plead provable facts strongly suggesting that the speaker did not believe that particular opinion to be true when uttered." In re Credit Suisse, 431 F.3d at 49. Plaintiff does not. Further, its challenges to forward-looking statements run afoul of the Reform Act.

A. Plaintiff Has Not Identified Any Materially False Statements

Plaintiff's challenge to statements concerning beliefs or opinions about the nature or possible outcome of the litigation or investigation does not state a claim. These statements are too general and subjective to be actionable. Further, most of them were demonstrably correct or subsequently validated. For example, the challenged statements that Medinol's trade secret theory would not "hold up" (CAC ¶ 63) and that the litigation would "get solved" (id. ¶ 64) are plainly non-actionable expressions of vague optimism and opinion. They also were not false.[5] The similar statement that the Company believed it acted "responsibly and appropriately" regarding the subject of the DOJ investigation (CAC ¶¶ 75, 83) is also too vague and subjective to be actionable. The statements that any defendants did not "see[] any nexus" between the DOJ investigation and the Taxus product line (id. ¶ 81), and that as a result did not "believe [the

[4] This rule insulating corporate puffery "applies to loose optimism about both a company's current state of affairs and its future prospects." Fitzer v. Sec. Dynamics Techs., Inc., 119 F. Supp 2d 12, 23 (D. Mass 2000).

[5] Medinol's trade secret theory of liability was in fact dismissed on summary judgment, see 346 F. Supp. 2d at 606-08, and the parties' contract dispute (which was all that remained) was in fact resolved.

investigation] implicates our business, as you know it today" (id.), are likewise both subjective and not alleged to be false.[6]

Plaintiff makes no effort to plead facts showing that the statements concerning the status of the Medinol litigation (CAC ¶¶ 64, 65, 68) were false. In December 2004, the Medinol court issued its summary judgment ruling, dismissing Medinol's tort claims and expressly stating that: "Essentially, this is a breach of contract case." Medinol, 346 F. Supp. 2d at 627. The court went on to say that, although the parties had "strained to enlarge this case, alleging ... many varieties of tort and grandiose estimates of damage[,] [i]t is unlikely that these claims can succeed ...." Id. Accordingly, the challenged statements describing the case as a "straight out contract" dispute, in which "grandiose" damage claims were "unlikely to succeed" (CAC ¶¶ 64, 65, 68), did no more than accurately describe what the Court had held. These statements were true, and nowhere in the Complaint is there any allegation to the contrary. They cannot therefore serve as the basis for a securities fraud claim. See Capri Optics Profit Sharing v. Digital Equip. Corp., 950 F.2d 5, 9-10 (1st Cir. 1991).

Plaintiff repeats Medinol's claim that Mr. Tobin supposedly told Medinol in 2000 that he was unaware when he joined the Company that he was involved with "crooks," and that he "was ashamed to represent such a dishonest company." (CAC ¶¶ 57, 62.) From this, plaintiff contends that defendants "knew" liability to Medinol was a certainty and so should have conceded defeat.

To the contrary, the Company was right to defend against Medinol's claims. Despite Medinol's (and plaintiff's) argument, Judge Hellerstein ruled on summary judgment that the matter was essentially a breach of contract case, and that Medinol's "grandiose estimates of damage" were unlikely to succeed. Medinol's tort and RICO claims were dismissed. See 346 F.

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[6] Plaintiff also purports to rely on two 2001 statements respecting the Medinol litigation, one describing Medinol's claims as "hav[ing] no merit," and the other stating that the suit "is all about leverage." (CAC ¶ 59.) These statements are outside of the class period and any claim based on them is time-barred. In re Ibis Tech. Sec. Litig., No. 04-10446-RCL, 2005 U.S. Dist. LEXIS 41490, at *43 n.19 (D. Mass. Sept. 22, 2005). In any event, they likewise are mere expressions of vague optimism and opinion, and are non-actionable for the same reasons that doom plaintiff's challenges to other statements respecting the Medinol litigation.

Supp. 2d at 627. What Tobin supposedly told Medinol in 2000 was hardly an admission as to facts known to him, and is of little moment, because he was not at the Company during the events giving rise to the Medinol dispute. (CAC ¶ 16.) Nor was it remotely dispositive regarding the legal merits of the "complex issues" presented by the parties' various contract, tort, common law, and statutory claims, and it had nothing to do with the truth or falsity of any of defendants' statements respecting the risks or status of the Medinol litigation. Moreover, as noted above, market participants were not misled by any supposed failure to admit liability; they concluded independently that Boston Scientific had exposure in the range of $1.5 billion. (See App. Exs. M-P.)

Similarly, the Complaint does not allege with particularity why any statements respecting the DOJ investigation were false. Two of the challenged statements were in response to an analyst's question in 2003 regarding whether there was a risk that the investigation could be related to Taxus. The unidentified speakers responded that they were not aware of any such connection: "I just haven't seen any nexus that relates to Taxus" (CAC ¶ 81); "it doesn't focus on any product we are selling today. We don't believe it implicates our business, as you know it today" (id.). The fact is that the investigation concerned the NORS stent, not the Taxus stent. The NORS stent had been long discontinued by 2003, when these statements were made. (Id.) These statements were not false, and the Complaint does not support a contrary conclusion.

Plaintiff alleges unpersuasively that it was misleading for the Company to state that it believed it had "acted responsibly and appropriately" (CAC ¶¶ 75, 83), and that the outcome of the DOJ investigation could be adverse (id. ¶ 82), because, according to plaintiff, defendants "knew" the opposite to be true. For this, plaintiff relies not any fact, but on an illogical inference. Plaintiff alleges that certain unnamed Boston Scientific officials (not the defendants) invoked their Fifth Amendment rights when asked in a civil disposition about the investigation, and concludes that the defendants therefore knew that the Company had not acted responsibly and that the investigation would certainly be adverse. (Id. ¶ 76.) This makes no sense. The fact that a witness in a civil case avoided waiving his Fifth Amendment rights in

connection with an ongoing DOJ investigation is hardly evidence that he "knew" the investigation had "merit." See, e.g., Carter v. Kentucky, 450 U.S. 288, 300 n.15 (1981) ("The Court has recognized that there are many reasons unrelated to guilt or innocence for declining to testify."). It says nothing about defendants' knowledge concerning how the investigation would be resolved.

Plaintiff cannot rely on a long discredited inference – "fraud by hindsight" – to claim that the subsequent Medinol and DOJ settlements are "proof" that earlier statements were misleading. (See CAC ¶¶ 70-74, 82-85.) Not only is this legally impermissible, see, e.g., Gross, 93 F.3d at 991; Fitzer, 119 F. Supp. 2d at 20, but it is illogical. Neither of the settlements constituted admissions of liability or wrongdoing. (See, e.g., App. Ex. W at p. 1.) The Medinol settlement was a typical civil settlement of disputed claims presenting myriad "complex issues," 346 F. Supp. 2d at 581, that, moreover, was favorably received by the securities markets (see App. Exs. M-P). The DOJ investigation was settled without any criminal charges being filed against anyone, and the government expressly acknowledged that the NORS stents did "not involve any risk to … patients." (App. Ex. W at p. 2.) Thus, these settlements are not a reasonable basis to conclude that defendants' earlier statements, denying liability but acknowledging that the outcome of the litigation and investigation might not be favorable (CAC ¶¶ 60-61, 75, 82, 83), were false.

B. The "Forward-Looking" Statements Are Not Actionable

In addition to the foregoing, plaintiff's claims predicated on the litigation and investigation are barred by the "safe harbor" provision of the Reform Act. A "forward-looking" statement is not actionable if it is "identified as … forward-looking … and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially …" 15 U.S.C. § 78u-5(c)(1)(A)-(B). All of the challenged statements concerning the potentialities related to the Medinol litigation and DOJ investigation (CAC ¶¶ 60, 61, 63, 64, 65, 68, 81, 83) were in SEC filings, analyst calls, and press releases that expressly identified the statements as forward-looking. (App. Ex. A at Exhibit 13.1, pp. 15-16; Ex. B at

Exhibit 13.1, pp. 30-31; Ex. C at pp. 15-16; Ex. S at p. 2; Ex. T at p. 5; Ex. U at pp. 6-7; Ex. V at p. 1; Ex. X.) Furthermore, the statements were accompanied by specific cautionary language that warned of the risks associated with those matters. Thus, for example, the 10-Ks warned that "the Company's performance may be affected by … The impact of [the] … Medinol Ltd. and other litigation, as well as the ultimate outcome of the U.S. Department of Justice Investigation." (App. Ex. A at Exhibit 13.1, pp. 15-16; Ex. B at Exhibit 13.1, pp. 30-31; Ex. C at pp. 15-16.) For this reason, none of the challenged misstatements respecting the Medinol litigation or DOJ investigation is actionable. Baron v. Smith, 380 F.3d 49, 54 (1st Cir. 2004).

In addition, as discussed above, plaintiff fails to plead particular facts demonstrating that any forward-looking statement "was made with actual knowledge … that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(A)-(B). For this independent reason as well, the challenged statements are not actionable. See Greebel, 194 F.3d at 201.

C. Defendants Were Not Required To Publicly Confess Judgment

As noted, Boston Scientific disclosed the Medinol litigation and the DOJ investigation, cautioned that favorable outcomes could not be assured, and advised that negative outcomes could adversely affect the Company. (App. Ex. A at Exhibit 13.1, pp. 15-16, 36, 41, 42; Ex. B at Exhibit 13.1, pp. 30-31, 60, 67, 68-69; Ex. C at pp. 15-16, 65, 67.) Plaintiff nevertheless seems to complain that the Company's disclosures were not sufficiently dour. Thus, plaintiff alleges that defendants "downplayed [the Medinol litigation's] significance and materiality" and "left the impression the suit had 'no merit,' or was a simple breach of contract case without 'grandiose' damages at stake," when, according to plaintiff, defendants "knew that [the litigation] exposed the Company to significant liability." (CAC ¶¶ 59-69.) Similarly, with respect to the DOJ investigation, plaintiff asserts that investors were misled because defendants disclosed that the investigation "'may' affect the Company when they knew it would affect the Company" (id. ¶ 82 (emphasis in original)), and because the Company stated it "believes that it acted responsibly and appropriately" even though it supposedly "knew" the investigation had "merit" (id. ¶¶ 76-77).

It is not the law that a public company engaged in contested litigation or that is the subject of a regulatory investigation is required to publicly profess the merit of its adversary's position. "[M]aintenance of ... innocence is not fraud. SEC rules to not create a duty to confess contested charges." Anderson v. Abbott Labs., 140 F. Supp. 2d 894, 906 (N.D. Ill. 2001), aff'd, Gallagher v. Abbott Labs., 269 F.3d 806 (7th Cir. 2001); see Anderson, 140 F. Supp. at 907 ("[Defendant] was entitled to put the FDA to its proof."); In re Citigroup, Inc. Sec. Litig., 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) ("the federal securities laws do not require a company to accuse itself of wrongdoing"); City Capital Assocs. Ltd. P'ship v. Interco, Inc., 696 F. Supp. 1551, 1556 (D. Del. 1988) ("Where there exists a good faith dispute as to facts or an alleged legal violation, the [law] only requires disclosure of the dispute."), aff'd, 860 F.2d 60 (3d Cir. 1988); Ballan v. Wilfred Am. Educ. Corp., 720 F. Supp. 241, 249 (E.D.N.Y. 1989) ("the SEC's proxy disclosure rules do not require a company's management to confess guilt to uncharged crimes ... There is no reason why a different rule should apply under §10(b)"). Boston Scientific disclosed the Medinol litigation and the DOJ investigation year after year in its 10-Ks, including procedural status updates, and cautioned that adverse outcomes could adversely affect the Company. That is all the securities laws (and common sense) required.

D. Any Claim Based On The Litigation Or The Investigation Is Barred Because The Market Knew The Facts Supposedly Omitted

Even were any of the misstatements or omissions identified in the Complaint respecting the Medinol litigation or DOJ investigation actionable, any claim based on them is barred because the information the Company supposedly hid from the market was in fact known to and absorbed by the market. An alleged "misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the market." Ganino v. Citizens Utils. Co., 228 F.3d 154, 167 (2d Cir. 2000). Here, because Boston Scientific disclosed the Medinol litigation and the DOJ investigation, and because the market already knew of the risks associated with those matters, none of the challenged statements respecting those matters can serve as the basis for a securities fraud claim.

In White v. H&R Block, 02 Civ. 2289, 2004 U.S. Dist. LEXIS 14522 (S.D.N.Y. July 27, 2004), the plaintiffs asserted that defendant H&R Block failed to adequately disclose litigation related to its refund loans and its potential liability in connection with that litigation. Like the plaintiff here, the plaintiffs in White conceded that H&R Block had disclosed the litigation, but argued that it only disclosed good news about the actions. In granting the motion to dismiss, the court held that any purported misstatements were immaterial as a matter of law because the truth about the litigation was well known:

> The [] litigation involved public lawsuits brought by public filings in public courts, and the litigation was the subject of extensive press coverage ... as well as press releases and SEC filings from Block itself. In short, the truth was all over the market.
>
> Further, the truth was available in the market with more intensity and credibility than was any purported misstatement from defendants. The truth about the [] litigation was available from the courts themselves, where the lawsuits were filed.

White, 2004 U.S. Dist. LEXIS, at **36-37 (emphasis added).[7]

As in White, the Company's Form 10-Ks throughout the class period disclosed the litigation and investigation, their subject matter, and stated that their outcome could adversely affect the Company's results. In addition, just as in White, there were newspaper articles throughout the class period concerning both the Medinol litigation and the DOJ investigation. (See, e.g., App. Exs. Y, Z, AA.) Indeed, articles on the Medinol litigation demonstrate that the market believed Boston Scientific's potential liability in that case was far greater than the ultimate settlement amount. (App. Ex. M.) As in White, the records in the Medinol litigation were publicly available at the courthouse – in fact, the court published written opinions. Just as dismissal of the complaint was mandated in White because "the truth was all over the market," so too here with regard to the Medinol litigation and the DOJ investigation.

[7] As the White court recognized, although truth-on-the-market is an affirmative defense, it is an appropriate ground for dismissal where, as here, "all the information plaintiffs claim was concealed by defendants was publicly available," thus rendering the "purported misstatements immaterial." White, 2004 U.S. Dist. LEXIS 14522, at *36; see also In re Colonial Mortg. Bankers Corp., 324 F.3d 12, 16 (1st Cir. 2003) ("In an appropriate case, an affirmative defense may be adjudicated on a motion to dismiss for failure to state a claim.").

III. The Complaint Fails To Allege With Particularity Any Actionable Misstatement Or Omission Respecting The Taxus Stents

Plaintiff also contends, based exclusively on hindsight, that statements regarding Taxus in the spring and summer of 2004 were misleading. (CAC ¶¶ 93, 94, 98, 101.) This is insufficient.

The Taxus stent was first introduced in Europe in January 2003. (CAC ¶ 87.) It was approved by the FDA and introduced in the U.S. market in March 2004. (Id. ¶ 92.) As the Complaint acknowledges, defendants contemporaneously disclosed reported complaints and problems respecting Taxus. Specifically, during a conference call with analysts in April 2004, the Company explained that there had been problems reported in the U.S. that were similar to those that had been reported in Europe following the European launch of the device. (Id. ¶ 93.) The Company's Form 10-Q filed one month later reported that the Company was "reviewing a limited number of reports related to balloon withdrawal difficulty during TAXUS angioplasty procedures." (Id.)

As noted, plaintiff must plead "facts that show exactly why the statements were misleading" when made. Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002). The Complaint contains not a single one. In fact, the Complaint acknowledges that the FDA in the summer of 2004 inspected the Company's two Taxus manufacturing facilities, and reported no observations. (CAC ¶ 105.)

Instead, plaintiff pleads in classic "fraud by hindsight" fashion that the later Taxus recall necessarily indicates that defendants "knew" beforehand that the problems "were much more significant" than reported. (CAC ¶ 95; see id. ¶ 101.) This is plainly inadequate: "there is no liability where a plaintiff's claim rests on the assumption that defendants 'must have known of the severity of their problems earlier because conditions became so bad later on.'" In re Boston Tech., Inc. Sec. Litig., 8 F. Supp. 2d at 53 (quoting Serabian v. Amoskeag Bank Shares, 24 F.3d 357, 367 (1st Cir. 1994)); see Gross, 93 F.3d at 994 (dismissing Section 10(b) claim because allegations did "not adequately support the inference that the company knew of these difficulties (or that they even existed) when it issued the [] press release"). Later problems are

not proof that defendants earlier committed securities fraud. See, e.g., W.R. Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 252 (D. Mass. 2001); Fitzer, 119 F. Supp. 2d at 22.

Plaintiff vainly tries to take its Taxus allegations out of the realm of hindsight by pointing to a manufacturing change made with respect to the stent. (CAC ¶ 95.) But this does not suggest that Boston Scientific knew about more serious problems or the need for a recall prior to the time those events actually occurred. Indeed, there is not even any allegation that the manufacturing change was initiated to correct the problem prompting the recall. To the contrary, as the Complaint notes, the change was in process before the launch and would have been made regardless whether any problems had been reported. (Id. ¶ 98.) Because it had nothing to do with the problems related to the recall, the manufacturing change is not evidence that defendants "knew" prior to the recall of more serious Taxus-related problems than were disclosed.

IV. The Complaint Fails To Allege With Particularity Any Actionable Misstatement Or Omission Related To The FDA Letters

Plaintiff also alleges that various statements related to the quality of the Company's medical devices were false and misleading. Specifically, plaintiff attacks:

- A statement regarding the Company's "rigorous laboratory testing" in a press release announcing FDA approval for Taxus enhancements. (CAC ¶ 108.)
- A statement by Mr. Best during an analyst call that the Company "is really burdened today by its enormous success." (Id. ¶ 115.)
- Statements in the Company's SEC filings that it was "committed to quality." (Id. ¶ 116.)
- A statement on the Company's website that its Glens Falls, New York facility is "world class" with "cutting edge automation." (Id. ¶ 119.)
- Statements in the Company's public filings that its "manufacturing process control initiative [had] strengthened the Company's technological resources to improve quality," and that "The Company is committed to providing high quality products to its customers. To meet this commitment, the Company has implemented state-of-the-art quality systems and concepts throughout the organization." (Id. ¶ 132.)

These statements are plainly "corporate puffery," and thus immaterial as a matter of law. Nor can plaintiff base its claim on the hindsight assertion that the subsequent FDA letters demonstrate that defendants "knew" these statements were false. And plaintiff is wrong in suggesting that Boston Scientific had an affirmative duty to disclose the FDA letters.

A. "Corporate Puffery" Is Immaterial As A Matter of Law

Plaintiff's attempt to base a securities fraud claim on the Company's touting its "rigorous laboratory testing," "commitment to quality," and "world class" and "state-of-the-art" systems is frivolous. These statements are so inherently vague and lacking in specificity "that no reasonable investor could believe them important to the total mix of information available." Shaw, 82 F.3d at 1217; see, e.g., Gross, 93 F.3d at 995 (statement that company had received "significant orders" not actionable); In re Allaire Corp. Sec. Litig., 224 F. Supp. 2d 319, 331 (D. Mass. 2002) (statement that product "exceeded our expectations" is "clear puffery and, therefore, not actionable"); Fitzer, 119 F. Supp. 2d at 23 (statements that company was "well positioned" was immaterial puffery); In re PLC Systems, Inc. Sec. Litig., 41 F. Supp. 2d 106, 120 (D. Mass. 1999) ("A statement by a company commending the 'potential' of its own product is hardly the stuff upon which reasonable investors base their decisions."); see also Orton v. Parametric Tech. Corp., 344 F. Supp. 2d 290, 301 (D. Mass. 2004) ("What company doesn't claim that its strong workforce, infrastructure, and product development position it well for future growth?").

B. Plaintiff Cannot Rely On Hindsight

Even if any of these statements could be considered potentially material, plaintiff pleads no fact demonstrating how they were subjectively or objectively false when made. Plaintiff's reliance on the subsequent FDA warning letters is mere hindsight. Gross, 93 F.3d at 994. In any event, those letters concerned technical reporting and monitoring issues at three of the Company's 26 worldwide facilities and said nothing about the quality of any of the Company's medical devices. (See CAC ¶¶ 110-12, 119, 121.)[8]

[8] Plaintiff also purports to rely on an FDA warning letter dated January 25, 2006. (CAC ¶¶ 128-29.) In addition to falling outside the class period, this letter likewise does not say anything about the quality of any of the Company's medical devices and thus cannot support plaintiff's hindsight allegations.

Plaintiff lamely contends that defendants' quality-related statements were "false" because the Company had undertaken a cost-cutting program and had reduced its workforce. (CAC ¶¶ 116, 131.) Companies do that all the time. See Fitzer, 119 F. Supp. 2d at 31. Under plaintiff's theory, it could always be pointed to as proof that the Company "knew" of a problem before the problem actually materialized. Cost-cutting and a commitment to quality are far from mutually exclusive. Moreover, the Complaint contains not a single specific allegation purporting to show that the Company's cost-cutting measures were in any way related to the issues identified by the FDA.

C. The Company Had No Affirmative Duty To Disclose The FDA Letters

Nor is there any merit to plaintiff's contention that Boston Scientific was required to disclose the FDA letters sooner than it did. As defined by the FDA itself, a warning letter is "informal and advisory." (App. Ex. R at 4-2.) "There is nothing magical about [an FDA] warning letter. Although the language sounds ominous, it really is rather boilerplate." Anderson, 140 F. Supp. 2d at 902 (dismissing Section 10(b) claim alleging a failure to disclose an FDA warning letter). As noted, the FDA letters were immediately posted on the FDA website and made publicly available, in accordance with FDA regulations. Moreover, the Complaint does not identify anything in or about the FDA letters – for example, that they impacted the Company's ability to manufacture or distribute any of its medical devices – alleged to have been material to the Company's operations. The letters thus imposed upon the Company no affirmative duty of independent disclosure. See Gallagher, 269 F.3d at 808 (affirming dismissal of Section 10(b) claim arising from failure to disclose FDA warning letter, noting: "We do not have a system of continuous disclosure. Instead firms are entitled to keep silent (about good news as well as bad news) unless positive law creates a duty to disclose.").

The warning letters identified not uncommon reporting and monitoring issues of the sort that must continuously be addressed by companies in heavily regulated industries. See In re Herbalife Sec. Litig., CV 95-400, 1996 U.S. Dist. LEXIS 11484, at *11 n.3 (C.D. Cal. Jan. 24, 1996) ("It is commonly known that [the] FDA ... issues untold numbers of warning

letters and informal communications"). Contrary to plaintiff's suggestion, they do not create disclosure obligations under the securities laws.

The precise issue was considered by the Second Circuit in Acito v. IMCERA Group, Inc., 47 F.3d 47 (2d Cir. 1995). In Acito, the FDA inspected IMCERA'S Kansas City plant on two separate occasions. After both inspections the FDA issued warning letters, the first identifying 34 deficiencies and the second identifying 14 deficiencies. The company did not disclose either. Subsequently, the FDA conducted a third inspection and issued a report identifying 85 deficiencies. The company suspended operations at that plant but failed to inform the investing public until one month later. The Second Circuit affirmed the district court's dismissal of the Section 10(b) claim and found that the results of the first two inspections were not material. The court noted that the Kansas City plant was one of over 30 operated by the defendant, the FDA did not take adverse action as a result of the first two inspections, and the company made commitments to remedy the deficiencies. Acito, 47 F.3d at 52. The court also noted that because the company was a worldwide manufacturer of products in a highly regulated industry, it would be "unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant." The court concluded that "[t]hese reports therefore were not material to the average investor." Id.

Similarly here, the inspections were conducted at three separate facilities (the Company has 26 worldwide) and Boston Scientific responded to the FDA's concerns in each instance. The letters contained the "boilerplate" language of the standard FDA warning letter. The three letters each identified six deficiencies – far less than the 14 and 34 deficiencies found immaterial in Acito. Just like in Acito, the letters did not result in any adverse action. The letters were immediately publicly available to the market, to analysts, and to investors through the FDA website. Indeed, two of the letters were discussed in the press shortly after being sent. (CAC ¶¶ 122, 124.) And the Complaint does not even allege that the letters actually impacted Boston Scientific's operations or its ability to manufacture or distribute any of its medical devices (because the letters did not).

For all of these reasons, the Company's non-disclosure of the FDA letters is not actionable. Indeed, any claim based on their supposed non-disclosure would be barred because the letters were immediately available to the public via the FDA website and, in fact, were the subject of press reports. The "truth" regarding the FDA letters thus was fully known to the market. See Yanek v. Staar Surgical Co., 388 F. Supp. 2d 1110, 1126 (C.D. Cal. 2005) (finding that information that was available through the FDA was publicly known and the market had the necessary information to assess its impact).

V. The Complaint Does Not Allege Specific Facts Giving Rise To A Strong Inference Of Scienter As To Any Of The Individual Defendants Or The Company

In addition to failing adequately to plead the threshold requirement of any actionable material misstatement or omission, the Complaint fails adequately to plead scienter. Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). The Reform Act requires that a securities fraud complaint state with particularity facts giving rise to a strong inference of scienter. 15 U.S.C. § 78u-4(b)(2); see Greebel, 194 F.3d at 196-97. Plaintiff must plead and the Court must evaluate separately the allegations of scienter as to each defendant. In re Lernout & Hauspie Sec. Litig., 208 F. Supp. 2d 74, 84 (D. Mass. 2002).

Plaintiff's conclusory allegations that defendants "knew" the true facts (assuming for purposes of the present discussion that the "true" facts differed from the disclosed facts) simply by virtue of their positions in the Company (CAC ¶¶ 134-35) are of no consequence. "[G]eneral averments of the defendants' knowledge of material falsity will not suffice." Serabian, 24 F.3d at 361 (internal citations and quotations omitted); see In re Stone & Webster, Inc. Sec. Litig., 414 F.3d 187, 205 (1st Cir. 2005) ("conclusory allegations as to the existence of knowledge are insufficient to provide the factual basis, supporting a strong inference of scienter, required by the PSLRA"); In re Sonus Networks, Inc. Sec. Litig., No. 04-10294-DPW, 2006 U.S. Dist. LEXIS 28272, at *78 (D. Mass. May 10, 2006) ("fraudulent intent cannot be inferred merely from the Individual Defendants' positions in the Company and alleged access to

information"); see also In re WRT Energy Sec. Litig., 96 Civ. 3610, 1999 U.S. Dist. LEXIS 3883, at *43 (S.D.N.Y. Mar. 31, 1999) (allegations that officer/director signed the annual report and was involved and familiar with issuer's day-to day operations "do not suffice to plead ... conscious misbehavior.").

Equally inconsequential are plaintiff's bald assertions to the effect that certain of the defendants had a motive to commit fraud because, for example, their compensation or the value of their stock options would increase if the Company's stock price increased. (CAC ¶¶ 137, 140-42.) "If scienter could be pleaded on that basis alone, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." Acito, 47 F.3d at 54. Accordingly, "such gauzy generalities, without more, are insufficient to plead scienter in a PSLRA case." In re Credit Suisse, 431 F.3d at 50; see Geffon v. Micrion Corp., 249 F.3d 29, 36 (1st Cir. 2001) ("an allegation that defendants had the motive and opportunity to make false or misleading statements is insufficient to support the 'strong inference' of scienter required [under] the PSLRA").

Most of plaintiff's effort to support a strong inference of scienter (and, indeed, most of the Complaint) relates to the Individual Defendants' stock sales. But "the mere fact that insider stock sales occurred does not suffice to establish scienter." In re Focus Enhancements, Inc. Sec. Litig., 309 F. Supp. 2d 134, 163-64 (D. Mass. 2001) (insider sales, though larger in volume than normal, did not support finding of scienter because timing was not suspicious; the "sales did not occur because of a big 'event' unknown to the public"). "At a minimum, the trading must be in a context where defendants have incentives to withhold material, non-public information, and it must be unusual, well beyond the normal patterns of trading by those defendants." Greebel, 194 F.3d at 198. Because "plaintiff's allegations must show a high likelihood of scienter," they "do not pass the 'strong inference' test when, viewed in light of the complaint as a whole, there are legitimate explanations for the behavior that are equally convincing." In re Credit Suisse, 431 F.3d at 48-49 (citing Greebel, 194 F.3d at 203). As to

none of the defendants do plaintiff's allegations suffice to raise the necessary "strong inference" of scienter.

A. Peter Nicholas

Peter Nicholas was Chairman of the Board during the class period, and formerly had served as the Company's CEO. (CAC ¶ 15.) He is not alleged to have made any of the allegedly misleading statements identified in the Complaint.

Aside from asserting that Donovan worked under Nicholas' direction (CAC ¶ 68), the only specific factual allegations respecting Nicholas are that he was CEO at the time of the NORS stent recall and during the underlying events giving rise to the Medinol litigation. (Id. ¶¶ 53, 58.) As noted, however, the DOJ investigation was resolved without any charges being brought against anyone, and the DOJ acknowledged that the NORS stents presented no risks to patients. (App. Ex. W at p. 2.) Moreover, most of Medinol's claims against the Company were dismissed in their entirety, as were all of Medinol's claims asserted against Nicholas individually. See 346 F. Supp. 2d at 611-12. Plaintiff's allegations cannot therefore give rise to a strong inference of scienter on Nicholas' part regarding either the Medinol litigation or the DOJ investigation. There are no allegations remotely connecting him to Taxus or the FDA letters. See In re Stone & Webster, 414 F.3d at 199 (complaint failed to allege scienter where it "provides nothing supporting the inference that either [defendant] was directly involved in the [misstatements], or had knowledge of the alleged falsity"); In re Sonus Networks, 2006 U.S. Dist. LEXIS 28272, at *49 n.15 ("Mere allegations of knowledge on the part of subordinates do not provide a sufficient basis for imputing knowledge to executives."). Nothing is added by plaintiff's allegation that Nicholas gifted approximately $9 million in stock during the class period (CAC ¶ 15), because it is not suggested that his doing so was out of the ordinary or otherwise suspicious. See, e.g., In re Focus Enhancements, 309 F. Supp. 2d at 163-64.

B. James Tobin

James Tobin was the President and a Director of the Company during the class period. (CAC ¶ 16.) The specific factual allegations respecting Tobin are that he supposedly

told Medinol in 2000 that he did not know when the joined the Company that he was working with "crooks" (id. ¶ 57), that he "downplayed" the Medinol litigation and DOJ investigation (id. ¶¶ 59, 64, 68, 74, 78, 82, 83), that he "pumped" the market with positive news about Taxus (id. ¶¶ 86, 90, 108), and that he failed to disclose the FDA warning letters (id. ¶ 115). The Complaint also alleges that Tobin put in place a cost-cutting plan and laid off employees to do so (id. ¶¶ 32-36), and that he brought in former co-workers from his prior company who were loyal to him in order to implement this plan (id. ¶¶ 39-40). For the same reasons that none of these allegations demonstrates the existence of any material misstatement or omission, they fail to demonstrate that Tobin knew of any falsity. See In re Credit Suisse, 431 F.3d at 53 ("the plaintiffs' failure satisfactorily to plead subjective falsity also supplies a solid basis for a finding that they have failed to satisfy the PSLRA standard for pleading scienter").

The Complaint also alleges that Tobin sold approximately $40 million in stock during the class period. (CAC ¶ 16.) This adds nothing to plaintiff's scienter allegations, because there is no allegation that Tobin's exercise of options and stock sales were unusual or suspicious. See In re Focus Enhancements, 309 F. Supp. 2d at 163-64. Further, as reflected in the Form 4s filed by Tobin during the class period, many of his sales were effectuated pursuant to a Rule 10b5-1 plan which removed control of the sales from Tobin and put them in the hands of a broker. (See App. Ex. F.) This indicates "that the sales were pre-scheduled and not suspicious." Weitschner v. Monterey Pasta Co., 294 F. Supp. 2d 1102, 1117 (N.D. Cal. 2003) (finding that complaint failed to plead scienter in part because defendants had 10b5-1 trading plans); Fener v. Belo Corp., 04-CV-1836-D, 2006 U.S. Dist. LEXIS 14376, at *67-68 (N.D. Tex. Mar. 30, 2006) (same); In re Netflix, Inc. Sec. Litig., No. C04-2978, 2005 U.S. Dist. LEXIS 18765, at *23 (N.D. Cal. June 23, 2005) (same); see In re Credit Suisse, 431 F.3d at 49 (no showing of scienter where there are "legitimate explanations for the behavior that are equally convincing").

C. Lawrence Best

The Complaint alleges that Lawrence Best was a Senior Vice President and Chief Financial Officer of the Company during the class period. (CAC ¶ 17.) He is alleged to have been involved in the underlying subject matter of the Medinol litigation (id. ¶ 58) (although, as with Nicholas, Medinol's claims against Best were dismissed, see 346 F. Supp. 2d at 611-12), to have improperly characterized the matter as a contract dispute (CAC ¶¶ 65-66), and to have failed to disclose the litigation in the Company's 10-Qs (although it was disclosed in the Company's 10-Ks (id. ¶¶ 60-61)). The Complaint also alleges that Best (may have) stated that he saw no connection between the DOJ investigation and Taxus (see id. ¶ 81), and charges him with touting the Company's prospects and reiterating its commitment to quality without disclosing the FDA letters (id. ¶¶ 115-16). As discussed above, none of these allegations suffices to demonstrate that Best made any material misstatements or omissions at all, much less that he did so with scienter. See In re Credit Suisse, 431 F.3d at 53.

The Complaint also alleges that Best exercised options and sold securities worth approximately $150 million during the class period. (CAC ¶ 17.) But this does not help plaintiff, because these allegations fail to account for the fact that Best had a stock option plan under which a million options were to expire in September 2003. (App. Ex. G.) In addition, most of Best's sales were made pursuant to a Rule 10b5-1 plan, further undermining an allegation that the trades were suspicious. (See App. Ex. G.) Because there are "legitimate reasons" explaining Best's exercise of options and stock sales, his stock sales cannot support a strong inference of scienter. See Greebel, 194 F.3d at 203, 206-07.

D. Paul LaViolette

The Complaint alleges that Paul LaViolette joined Boston Scientific in 1994 as President of Boston Scientific International and became Chief Operating Officer in 2004. (CAC ¶ 18.) The only specific allegations concerning him are that he described how well Taxus had been received following its introduction (id. ¶ 90), that he disclosed the number of complaints regarding Taxus and described them as an "extremely low complaint rate" (id. ¶ 93), and that he

stated that "you are dealing with simple lag time in the marketplace conversion of new products, not necessarily a continuation of complaints from the new issue product" (id. ¶ 101). As discussed above, aside from hindsight, the Complaint contains no allegation indicating how or why LaViolette could have known these statements to be false. See Lirette v. Shiva Corp., 27 F. Supp. 2d 268, 283 (D. Mass. 1998) (allegations that defendants should have known about problems by virtue of their position at the company insufficient to plead scienter). Moreover, there are no allegations in the Complaint whatsoever that could even remotely indicate the LaViolette knew of the falsity of any alleged misstatement respecting the Medinol litigation, the DOJ investigation, or related to the issues raised in the FDA letters.

The allegations of LaViolette's stock sales do not contribute to a strong inference of scienter. The Complaint alleges that LaViolette sold stock worth $14 million during the class period, representing 29% of the shares and options he held. (CAC ¶ 18.) But this cannot demonstrate scienter because, as plaintiff admits (see id. ¶ 148), LaViolette's trading practices were the same before the class period. See Greebel, 194 F.3d at 206-07. Moreover, many of his sales were made pursuant to a Rule 10b5-1 plan. (See App. Ex. H.)

E. Fredericus Colen

The only allegations in the Complaint concerning Fredericus Colen are that he became Senior Vice President and Chief Technology Officer of Boston Scientific in July 2001 and that he sold more than $24 million in stock during the class period. (CAC ¶ 19.) The isolated allegation concerning Colen's position at the Company is meaningless. In re Cytyc Corp. Sec. Litig., No. 02-12399-NMG, 2005 U.S. Dist. LEXIS 6166, at *105 (D. Mass. Mar. 1, 2005) (position in company and access to information insufficient to plead scienter). So too is the allegation regarding his stock sales. Not only were many of them made pursuant to a Rule 10b5-1 plan (see App. Ex. I), but where a defendant "did not make any of the allegedly misleading statements ... stock sales do not give rise to a strong inference of deliberate recklessness." In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 988 (9th Cir. 1999).

F. Stephen Moreci

Similarly, the only allegations concerning Stephen Moreci are that he served as Senior Vice President and Group President of Endosurgery and that he sold $20 million worth of Company stock during the class period. (CAC ¶ 20.) Again, these paltry allegations are woefully insufficient to give rise to a strong inference of scienter. See In re Stone & Webster, 414 F.3d at 205-06; In re Focus Enhancements, 309 F. Supp. 2d at 163-64; In re Silicon Graphics, 183 F.3d at 988.

G. Paul Sandman

The Complaint alleges that Paul Sandman was Senior Vice President, Secretary and General Counsel of Boston Scientific during the class period. (CAC ¶ 21.) The only specifics pled respecting Sandman are that he stated "I don't frankly think that [Medinol's theft of trade secrets] theory is going to hold up" (id. ¶ 63), he (may have) stated that he did not see a nexus between the DOJ investigation and Taxus (see id. ¶ 81), and he supposedly participated in misleading investors because the Company stated in SEC filings that it believed it acted appropriately and responsibly in the matter under investigation by the DOJ (id. ¶ 82). For the reasons discussed above, the Complaint fails to plead that these statements were even false, much less that Sandman knew them to be false. See In re Credit Suisse, 431 F.3d at 53. Moreover, there are no allegations whatsoever connecting Sandman to the challenged statements related to Taxus and the subjects of the FDA letters.

The Complaint also alleges that Sandman sold approximately $24 million of Company stock during the class period. (CAC ¶ 21.) But because many of these sales were effectuated pursuant to a Rule 10b-5 plan (see App. Ex. J), they cannot support a strong inference of scienter.

H. James Taylor

The Complaint alleges that James Taylor was the Company's Senior Vice President of Corporate Operations from August 1999 until January 2006. (CAC ¶ 22.) The only specific allegations concerning Taylor are that he was loyal to Tobin (id. ¶ 39), he knew the

consequences of negative publicity on stock price based on his prior position at another company (id. ¶ 40), he had authority over manufacturing operations and working with regulators (id. ¶ 41), and he left the Company shortly after it received the FDA letters (id. ¶ 42). These vague and conclusory allegations cannot support a strong inference that Taylor acted with intent to deceive or manipulate or knew of the supposed falsity of any claimed misstatement. See In re Stone & Webster, 414 F.3d at 205-06; In re Sonus Networks, 2006 U.S. Dist. LEXIS 28272, at *42.

The Complaint further alleges that during the class period Taylor exercised options and sold stock worth $15 million. (CAC ¶ 22.) This allegation does not add to plaintiff's otherwise nonexistent scienter allegations as against Taylor, especially given that he is not alleged to have made any allegedly misleading statements, In re Silicon Graphics, 183 F.3d at 988, and there are no allegations that the timing of sales were suspicious or occurred because of some big event unknown to the public, In re Focus Enhancements, 309 F. Supp. 2d at 163-64.

I. Robert MacLean

The only allegations respecting Robert MacLean are that he was Vice President of Human Resources at Boston Scientific until March 2005 and that he exercised options and sold stock valued at $26 million during the class period. (CAC ¶ 23.) These vague and non-substantive allegations concerning MacLean's position and his stock sales do not support a strong inference of scienter. In re Focus Enhancements, 309 F. Supp. 2d at 163-64; In re Cytyc Corp., 2005 U.S. Dist. LEXIS 6166, at *105; In re Silicon Graphics, 183 F.3d at 988. Moreover, some of the stock sales were made pursuant to a Rule 10b5-1 plan. (See App. Ex. K.)

J. Boston Scientific

Because plaintiff has failed to plead scienter as against any of the Individual Defendants, it has not pled scienter as against Boston Scientific. Moreover, because all of the subjects about which plaintiff complains were disclosed in the Company's public filings, "albeit not to the degree plaintiffs insist was necessary ... the record fails to reflect a strong inference that [the company] knew that the statements were false or materially misleading ...." In re Cytyc Corp., 2005 U.S. Dist. LEXIS 6166, at *102; see Geffon, 249 F.3d at 37 ("Perhaps Micrion

could have provided still more information ... however, absent the type of evidence we have previously found probative of scienter, its failure to do so does not mean that the omission was purposely deceptive in a manner actionable under Rule 10b-5"); In re Parametric Tech. Corp., 300 F. Supp. 2d 206, 216 (D. Mass. 2001) ("... the omission of a relatively immaterial fact might well have been done precisely because it was immaterial. So failure to plead sufficiently the materiality of the omitted information goes a long way toward dooming an assertion that the omission was intended to deceive.").

VI. The Complaint Does Not Allege Loss Causation

The Complaint also fails to plead a third required element of a securities fraud claim, loss causation. To satisfy this element, plaintiff must plead "a causal connection between the material misrepresentation and the loss." Dura, 544 U.S. at 342. It is not enough merely to allege that securities were purchased at an inflated price. Id. Instead, plaintiff must allege that its "loss [was] caused by the materialization of [a] concealed risk." Lentell, 396 F.3d at 173. Plaintiff cannot do so here, because the risks that caused the claimed loss were disclosed and well known to the market.

In Lentell, plaintiffs alleged that Merrill Lynch issued false recommendations on certain internet companies, thereby inflating their stock price. 396 F.3d at 173. Plaintiffs claimed that they purchased their stock at inflated prices and were damaged when the stock later declined in value. Id. at 175. In affirming the district court's dismissal, the Second Circuit held that no loss causation was alleged because Merrill Lynch had disclosed that the companies were "volatile investments, and therefore subject to sudden and substantial devaluation risk." Id. at 176. Given this disclosure, the plaintiffs were required to (but did not) plead facts sufficient to show that it was the alleged fraud, rather than the realization of the disclosed risk, that proximately caused their claimed harm, or facts sufficient to apportion the losses between the disclosed and concealed portions of the risk. Id. at 177. The situation here is the same.

With respect to each of the subjects about which plaintiff complains, the claimed "loss" was the result of a materialization of previously disclosed risks:

Claimed Loss Event	**Previously Disclosed Risk**
Medinol Litigation Settlement	"Certain factors that could cause actual results to differ materially from those expressed in forward-looking statements are contained below. … The impact of stockholder, patent, product liability, Medinol and other litigation, as well as the ultimate outcome of the U.S. Department of Justice investigation." (App. Ex. A at Exhibit 13.1, pp. 15-16; Ex. B at Exhibit 13.1, pp. 30-31; Ex. C at pp. 15-16.)
Settlement of DOJ Investigation	See above. "There can be no assurance that the investigation will result in an outcome favorable to the Company, that charges would not be brought, or that the Company would not agree to a further extension of the statute." (App. Ex. A at Exhibit 13.1, p. 42; Ex. B at Exhibit 13.1, pp. 68-69; Ex. C at p. 67.)
Taxus Recall	"[T]he Company's performance may be affected by: -- the Company's ability to prevent disruptions in its TAXUS manufacturing processes and to maintain inventory levels consistent with customer demand around the world." (App. Ex. B at Exhibit 13.1, p. 30; Ex. C p.15.) The Company's success with drug eluting stents (i.e., Taxus) could be adversely affected by "unexpected variations in clinical results or product performance," and "[t]he Company is currently reviewing a limited number of reports related to balloon withdrawal difficulty during TAXUS angioplasty procedures." (App. Ex. D at p. 22.)
FDA Warning Letters	"The medical devices manufactured and marketed by the Company are subject to regulation by numerous regulatory bodies, including the FDA … Failure to comply with regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations." (App. Ex. A at pp. 22-24; Ex. B at pp. 17-19; Ex. C at pp. 11-12.)

In the face of these risk disclosures, plaintiff cannot plead and has not pleaded how any supposed misstatement or omission "concealed something from the market that, when disclosed, negatively affected the value of the security." Lentell, 396 F.3d at 178. An efficient market, such as is alleged with respect to the Company's securities (see CAC ¶ 151), necessarily absorbs and takes into consideration all information available to it. Basic Inc. v. Levinson, 485

U.S. 224, 247 (1988) ("most publicly available information is reflected in market price"). For that reason, loss causation cannot be predicated on the realization of a previously disclosed risk. See In re Alkermes Sec. Litig., No. 03-12091-RCL, U.S. Dist. LEXIS 25826, at *36 (D. Mass. Oct. 6, 2005) ("In the absence of any allegation that the manufacturing-related allegations 'concealed something from the market that, when disclosed, negatively affected the value of the security,' the Plaintiffs have failed to allege an element of their claim, loss causation.").

VII. No Claim Has Been Stated For Control Person Liability Under Section 20(a)

Because plaintiff has failed to allege a primary violation of Section 10(b), the Section 20(a) claim for control person liability also fails. See Parametric Tech., 300 F. Supp. 2d at 224; In re Peritus Software Servs., Inc. Sec. Litig., 52 F. Supp. 2d 211, 230 (D. Mass. 1999). In addition, the "control" allegations are purely conclusory. (See CAC ¶¶ 14, 170.)

Moreover, the Complaint fails to allege a violation of Section 20(a) because plaintiff has not adequately pled "culpable participation" by the Individual Defendants.[9] For the same reasons that the Complaint insufficiently pleads scienter, it insufficiently pleads that the Individual Defendants knowingly, actively, or meaningfully participated in making any material misstatement with actual knowledge of its falsity. See SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996).

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[9] Although the First Circuit has not addressed whether "culpable participation" is an element of a Section 20(a) claim, see In re Stone & Webster, 414 F.3d at 196 n.6, several courts have held that it is, see, e.g., First Jersey Sec. Inc., 101 F.3d at 1472; Sharp v. Coopers & Lybrand, 649 F.2d 175, 185 (3d Cir. 1981).

CONCLUSION

For the forgoing reasons, defendants respectfully request that this Court grant their motion to dismiss in its entirety and dismiss plaintiff's Complaint, with prejudice.

Respectfully Submitted,

Dated: June 8, 2006

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CERTIFICATE OF SERVICE

I, Kirsten M. Nelson, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent by mail to those indicated as non-registered participants on June 8, 2006.

/s/ Kirsten M. Nelson
Kirsten M. Nelson (BBO# 634520)

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